IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Kalpana Kamath et al.	Art Unit	: 1793
Serial No.	: 10/814,079	Examiner	: Pegah Parvini
Filed	: March 30, 2004	Conf. No.	: 5482
Title	: EMBOLIZATION		

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Commissioner for Patents
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BRIEF ON APPEAL

(1) Real Party in Interest

Boston Scientific Scimed, Inc.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 4-9, 11-13 and 21-25 are pending, have been twice rejected, and are presented for appeal.

Claims 1-3, 10, 14-20 are cancelled.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

Claims 4, 21 and 24 are the independent claims.

Independent claim 4 covers a composition that includes a plurality of substantially spherical porous silica particles.[1] At least some of the plurality of substantially spherical silica

[1] *See, e.g.*, 10/814,079, p. 1, lines 14-15.

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particles having a diameter of from about 100 microns to about 3000 microns.[2] The composition also includes a carrier fluid.[3] The plurality of substantially spherical porous particles are in the carrier fluid.[4] For at least some of the plurality of substantially spherical porous silica particles, a pore volume of the substantially spherical porous silica particles is from about 0.4 ml/g to about 1.6 ml/g.[5] The plurality of substantially spherical porous silica particles have a pore volume distribution such that about 70% or more of the pore volume of the plurality of substantially spherical porous silica particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.[6] Claims 5-9 and 11-13 depend from claim 4.

Independent claim 21 covers a composition that includes a plurality of substantially spherical porous silica particles.[7] At least some of the plurality of substantially spherical silica particles having a diameter of from about 100 microns to about 3000 microns.[8] The composition also includes a carrier fluid.[9] The plurality of substantially spherical porous particles are in the carrier fluid.[10] For at least some of the plurality of substantially spherical porous silica particles, the density of the particles is from about 1.1 grams per cubic centimeter to about 1.4 grams per cubic centimeter.[11] The carrier fluid comprises a saline solution. Claims 22 and 23 depend from claim 21.

Independent claim 24 covers a composition that includes a plurality of substantially spherical porous silica particles.[12] At least some of the plurality of substantially spherical silica particles having a diameter of from about 100 microns to about 3000 microns.[13] The composition also includes a carrier fluid.[14] The plurality of substantially spherical porous

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[2] *See, e.g., id.*, lines 15-17.
[3] *See, e.g., id.*, lines 14-15.
[4] *See, e.g., id.*
[5] *See, e.g., id.*, p. 2, lines 4-6.
[6] *See, e.g., id.*, lines 7-9.
[7] *See, e.g., id.*, p. 1, lines 14-15.
[8] *See, e.g., id.*, lines 15-17.
[9] *See, e.g., id.*, lines 14-15.
[10] *See, e.g., id.*
[11] *See, e.g., id.*, p. 2, lines 4-6.
[12] *See, e.g., id.*, lines 14-15.
[13] *See, e.g., id.*, lines 15-17.
[14] *See, e.g., id.*, lines 14-15.

particles are in the carrier fluid.[15] The plurality of substantially spherical porous silica particles have a pore volume distribution such that about 70% or more of the pore volume of the plurality of substantially spherical porous silica particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.[16]

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 4-8, 11-13, 24 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chevallier et al., U.S. Patent No. 6,468,493 ("Chevallier") in view of Mangin et al., US 2003/0206864 ("Mangin").

Claims 4, 9 and 21-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kirkland et al., U.S. Patent No. 6,482,324 ("Kirkland") in view of Mangin.

(7) Argument

Rejection of claims 4-8, 11-13 and 24-25 under 35 U.S.C. §103(a)
as being unpatentable over Chevallier in view of Mangin

Claims 4-8, 11-13, 24 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chevallier in view of Mangin. But, it would not have been obvious to one skilled in the art to combine Chevallier and Mangin in the manner indicated by the Examiner to provide the subject matter covered by claims 4-8, 11-13, 24 and 25. On the one hand, Chevallier discloses precipitated particles designed for use as a reinforcing filler in elastomers (*wee, e.g.,* Chevallier, Abstract), and Chevallier has nothing whatsoever to do with embolization. On the other hand, Mangin discloses particles designed for use in embolization (*see, e.g.,* Mangin, Abstract), and Mangin has nothing whatsoever to do with reinforcing fillers for elastomers. As explained by the United States Court of Appeals for the Federal Circuit:

> to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then

[15] *See, e.g., id.*
[16] *See, e.g., id.*, p. 2, lines 7-9.

> be reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992); *see also* MPEP §2141.01(a).

Simply put, Chevallier is not reasonably pertinent to the problem with which Mangin was concerned, and Mangin is not reasonably pertinent to the problem with which Chevallier was concerned. Thus, Chevallier is non-analogous art to Mangin. Accordingly, the Examiner's proposed combination of Chevallier and Mangin is improper.

The Examiner responded to this argument by indicating that Appellant needs to show:

> tangible evidence on why the silica of Chevallier et al. cannot be used as embolic particles in the composition of Mangin even though Mangin clearly teaches the use of fine silica particles in said invention. *See* the Office Action mailed October 15, 2009 ("the Office Action"), p. 15.

Appellant is unaware of legal support for this position. Certainly, the Examiner has not provided any. Appellant believes that, if the Examiner is to maintain this position, the Examiner must provide legal support for the position. In the absence of such legal support, Appellant believes the Examiner must retract this statement.

Further, claims 4-8, 11-13, 24 and 25 require the particles to have a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter. Neither Chevallier nor Mangin explicitly disclose that their particles have such a pore volume distribution. To the extent that the Examiner's intent is to establish that one or both of the references inherently disclose particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter, the Examiner is reminded that, as explained in MPEP §2112 (emphasis in original):

> The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily

present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Here, the Examiner has not met the requisite burden to establish that either Chevallier or Mangin disclose particles having a pore volume distribution such that about 70% or more of the pore

volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore, as required by claims 4-8, 11-13, 24 and 25. Thus, the Examiner has failed to establish that, even it would have somehow been obvious for one skilled in the art to combine Chevallier and Mangin in the manner indicated by the Examiner, the result would have been the subject matter would have been the subject matter covered by these claims.

In response, the Examiner said:

> Although Mangin may not literally disclose all the detailed limitations of the recited claims, said reference discloses the use of "fine" silica particles, and this is seen to broadly include any and all silica particles specially considering the fact that Chevallier et al., in fact, disclose the pore size, pore volume and particle size of silica particles. *See* the Office Action, p. 16.

Appellant again refers the Examiner to the above-noted legal standard for establishing inherent disclosure, and reiterate their position that the Examiner has failed to satisfy the burden of establishing that either Chevallier or Mangin inherently disclose the particles covered by claims 4-8, 11-13, 24 and 25. Without conceding the Examiner has accurately characterized the disclosure of either Mangin or Chevallier, Appellant is unaware of any legal support for the notion that a reference that discloses "any and all silica particles" would satisfy the standard for inherently disclosing particles having the particular pore volume distribution required by these claims. Nor has the Examiner cited any such legal support. Here again, Appellant believes that the Examiner must either provide appropriate legal support or withdraw the Examiner's argument. Further, while it may be the case that Chevallier discloses certain characteristics of his particles, he (like Mangin) simply does not explicitly or inherently disclose the particular pore volume distribution required by claims 4-8, 11-13, 24 and 25.

Moreover, out of the innumerable particles that are potentially disclosed in Chevallier and Mangin, there is nothing in either reference that would have rendered it obvious to use particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore, as required by claims 4-8, 11-13, 24 and 25. The Examiner seems to indicate that, because the prior art allegedly discloses particles having a size that overlaps with

the particle size required by these claims, it follows that the prior art particles have the pore volume distribution required by these claims. *See id.*, p. 5. But, the Examiner has provided no evidence to support this logic. In fact, as would be readily understood by one skilled in the art, particles of a given size can have very different pore volume distributions. In addition, the Examiner cites certain cases in an apparent attempt to shift the burden to Appellant to demonstrate that Chevallier's particles do not inherently possess Appellant's claimed pore volume and tolerance. *See id.* But, the Examiner's reliance on *Spada* and *Fitzgerald* is improper because those cases are properly applied under very different facts, where, for example, the Examiner has established that the claimed product and the prior art product are substantially the same. *See, e.g.*, MPEP §§2112 and 2112.01. Here, the Examiner has not established that Chevallier's particles are substantially the same as Applicant's claimed particles. The Examiner's reliance on *Swinehart* is also improper as this case seems inapposite to the facts presented here. Moreover, the Examiner cites MPEP §2145 in an attempt to shift the burden to Appellant to disprove the Examiner's tenuous obviousness argument. *See id.*, p. 15. Appellant reminds the Examiner that MPEP §2145 refers to a shifting of the burden "***if a prima facie case of obviousness is established*** ...." *See* MPEP §2145. Because the Examiner has not properly established a prima facie case of obviousness, it is improper for the Examiner to try to shift the burden to Appellant in the manner indicated in the Office Action.

Limitations in various dependent claims provide additional bases for patentability. As an example, claims 11 and 25 recite that the particles exhibit a loss of attrition resistance of about 0.1% by weight or less. Neither Chevallier nor Mangin explicitly disclose that their particles have such a loss of attrition resistance. Here again, the Examiner's approach to trying to establish inherent disclosure in Chevallier is improper, for reasons similar to those noted in the preceding paragraph.

In view of the foregoing, Appellant requests reconsideration and withdrawal of the rejection of claims 4-8, 11-13, 24 and 25.

Rejection of claims 4, 9 and 21-23 under 35 U.S.C. §103(a)
as being unpatentable over Kirkland in view of Mangin

Claims 4, 9 and 21-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kirkland in view of Mangin. However, it would not have been obvious to one skilled in the art to combine these references to provide the subject matter covered by claims 4, 9 and 21-23. On the one hand, Kirkland discloses porous silica containing certain functional groups that can selectively bind to reaction impurities (*see, e.g.,* Kirkland, Abstract), and Chevallier has nothing whatsoever to do with embolization. Thus, Kirkland is not reasonably pertinent to the problem with which Mangin was concerned, and Mangin is not reasonably pertinent to the problem with which Kirkland was concerned. As a result, Kirkland is non-analogous art to Mangin, and the Examiner's proposed combination of Kirkland and Mangin is improper. *See, e.g., Oetiker* at 1443; *see also* MPEP §2141.01(a).

Further, claims 22, 24 and 25 require the particles to have a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter. Neither Kirkland nor Mangin explicitly or inherently disclose such subject matter. *See, e.g.,* MPEP §2112. Therefore, without conceding that it would have been obvious to one skilled in the art to combine these references in the manner indicated by the Examiner, even if such a combination would have been obvious, the Examiner has not established that the result would have been the subject matter covered by claims 22, 24 and 25.

In addition, claims 23 and 25 recite that the particles exhibit a loss of attrition resistance of about 0.1% by weight or less. Neither Kirkland nor Mangin explicitly disclose that their particles have such a loss of attrition resistance. Here again, the Examiner's approach to trying to establish inherent disclosure in Kirkland is improper, for reasons similar to those noted above.

In view of the foregoing, Appellant requests reconsideration and withdrawal of the rejection of claims 4, 9 and 21-23.

The brief fee of $540 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: November 18, 2009

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Appendix of Claims

1. (Cancelled).

2. (Cancelled).

3. (Cancelled).

4. (Previously Presented) A composition, comprising:

a plurality of substantially spherical porous silica particles, at least some of the plurality of substantially spherical silica particles having a diameter of from about 100 microns to about 3000 microns; and

a carrier fluid, the plurality of substantially spherical porous particles being in the carrier fluid,

wherein:

for at least some of the plurality of substantially spherical porous silica particles, a pore volume of the substantially spherical porous silica particles is from about 0.4 ml/g to about 1.6 ml/g; and

the plurality of substantially spherical porous silica particles have a pore volume distribution such that about 70% or more of the pore volume of the plurality of substantially spherical porous silica particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.

5. (Original) The composition of claim 4, wherein the carrier fluid comprises a saline solution.

6. (Original) The composition of claim 4, wherein the carrier fluid comprises a contrast agent.

7. (Original) The composition of claim 4, wherein at least some of the plurality of substantially spherical porous silica particles have a diameter of at most about 1500 microns.

8. (Original) The composition of claim 4, wherein, for at least some of the plurality of substantially spherical porous silica particles, pores in the substantially spherical porous silica particles have a diameter of from about 20 nanometers to about 90 nanometers.

9. (Previously Presented) The composition of claim 4, wherein, for at least some of the plurality of substantially spherical porous silica particles, the density of the particles is from about 1.1 grams per cubic centimeter to about 1.4 grams per cubic centimeter.

10. (Cancelled).

11. (Original) The composition of claim 4, wherein the substantially spherical porous silica particles exhibit a loss of attrition resistance of about 0.1% by weight or less.

12. (Original) The composition of claim 4, wherein at least some of the plurality of substantially spherical porous silica particles include a material selected from the group consisting of therapeutic agents, ferromagnetic materials, MRI visible materials and radiopaque materials.

13. (Original) The composition of claim 4, wherein the plurality of substantially spherical porous silica particles are sterilized.

14. (Cancelled).

15. (Cancelled).

16. (Cancelled).

17. (Cancelled).

18. (Cancelled).

19. (Cancelled).

20. (Cancelled).

21. (Previously Presented) A composition, comprising:

a plurality of substantially spherical porous silica particles, at least some of the plurality of substantially spherical silica particles having a diameter of from about 100 microns to about 3000 microns; and

a carrier fluid, the plurality of substantially spherical porous particles being in the carrier fluid,

wherein, for at least some of the plurality of substantially spherical porous silica particles, the density of the particles is from about 1.1 grams per cubic centimeter to about 1.4 grams per cubic centimeter, and the carrier fluid comprises a saline solution.

22. (Previously Presented) The composition of claim 21, wherein the plurality of substantially spherical porous silica particles have a pore volume distribution such that about 70% or more of the pore volume of the plurality of substantially spherical porous silica particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.

23. (Previously Presented) The composition of claim 21, wherein the substantially spherical porous silica particles exhibit a loss of attrition resistance of about 0.1% by weight or less.

24. (Previously Presented) A composition, comprising:

a plurality of substantially spherical porous silica particles, at least some of the plurality of substantially spherical silica particles having a diameter of from about 100 microns to about 3000 microns; and

a carrier fluid, the plurality of substantially spherical porous particles being in the carrier fluid,

wherein the plurality of substantially spherical porous silica particles have a pore volume distribution such that about 70% or more of the pore volume of the plurality of substantially spherical porous silica particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.

25. (Previously Presented) The composition of claim 24, wherein the substantially spherical porous silica particles exhibit a loss of attrition resistance of about 0.1% by weight or less.

Evidence Appendix

None.

Related Proceedings Appendix

None.